Method Sheet 17
Data Integrity and Good Laboratory Practice

Overview

Adhering to high standards of experimental conduct, and maintaining transparent records of your work are core requirements of Good Laboratory Practice (GLP). Adhering to the principles of Data Integrity furthermore ensures that your findings are reproducible, traceable, and “audit-ready”. Being aware of these principles and adhering to them are two of the most critical skills sought by employers in the life science industries.

Core principles of Data Integrity

Professional laboratory workers commonly adhere to the ALCOA+ principles for data integrity. These state that the records of your work should always be:

Attributable: It should be clear who performed every measurement - always sign and date your lab book entries and raw data printouts.
Legible: Records must be readable. If using a physical lab book, use permanent ink; if digital, ensure clear file-naming conventions.
Contemporaneous: Record your data at the time of the experiment. Don’t rely on memory to fill in your lab book later in the day.
Original: Always keep your "Raw Data" (the original .csv or .xlsx export from the plate reader). Never work directly on the master file; save a copy as a "Working File" for your calculations, and move this file into a separate folder for data analysis.
Accurate: Ensure all units (e.g., µM vs mM) and dilutions are double-checked and recorded.
Plus: Data should also be Complete, Consistent, Enduring, and Available.

Core principles of Data Management

Professional laboratory workers are also expected to store and manage data to a high standard, adhering to the following principles throughout a project:

1. Use an appropriate data file storage structure

You should create an appropriate folder structure for your project. For example, you could name the folders for a particular project as follows:
Folder 01: Raw Data (untouched, as it came from the instrument)
Folder 02: Processed Data (collation / calculations / statistical analyses)
Folder 03: Final Figures (charts for dissertation)

2. Use a systematic naming scheme for data files

Use file names that contain essential information necessary to identify the specific experiment conducted, in a way that can be easily matched to your laboratory notes. For example, avoid using names like “`final_results_v2.xlsx`”.

Instead, choose a self-explanatory format, such as: YYYYMMDD_ProjectName_AssayType_Initials_v01, for example: “`20260402_Phytotitre_M.luteus_JS_plate02.xlsx`”

This example is much better as it contains the date, the type of experiment, the operator’s initials and the experiment number. Note that it is helpful to use the ISO format for dates (YYYY-MM-DD) to avoid confusion between UK and US date styles.

3. Record appropriate metadata for each plate run

For every 96-well plate read, record the Plate ID, Date, Incubation Time, and Library Lot Number. Also mention the instrument settings, such as wavelength, shake time and gain settings. An easy way to do this is to type it into a spare cell of the Excel file after collecting the data from the instrument.

4. Use a clear and consistent protocol to label "mistakes"

In GLP data management, we do not delete data that may appear unusal or outwith the expected range. If such a measurement is seen, such as may happen due to pipetting errors or contamination events, cross it out with a single line (so the original is still visible), initial it, and write a brief note (e.g., "error: bubble in well A10"). If you choose to exclude a specific data point as an outlier, you must do so following a pre-defined criteria (e.g., the Dixon's Q-test or Grubbs' test), and document why the point was excluded in the working analysis file and your laboratory notebook.

5. Data Storage & Security

UK Data Protection (GDPR) and University policies require secure storage of data. This should typically involve storing your research data on a secure, university-backed cloud drive (e.g., OneDrive or SharePoint). You should also keep a backup of this data on a separate University-managed hard drive or server. Note that USB sticks are for transport of data from instrument to PC, not for long-term storage. They are easily lost and prone to data leaks and hardware failure. Move data from USB sticks to a secure server location as soon as possible.

Core principles of Good Laboratory Practice (GLP)

Good Laboratory Practice (GLP) is a quality system controlling how laboratory studies are planned, performed, monitored, recorded, archived and reported. While full "Regulatory GLP" is a formal legal requirement for pre-clinical drug safety trials, adopting GLP principles in an academic or discovery setting ensures that your results are credible, reproducible and ready for publication or an excellent dissertation.

The core Principles of Good Laboratory Practice (GLP) are as follows:

1. Personnel and Organisation

Every individual in the lab must have a clear role, for example:

Study Director: Your supervisor, the single point of control for the study.

Analyst: You, the student, are responsible for following the protocols exactly as written and recording any deviations. You should also maintain a record of your competencies (e.g., "Signed off for Class II MSC use").

2. Strictly follow the Standard Operating Procedures (SOPs)

GLP relies on the fact that an experiment should yield the same result regardless of who performs it, provided they follow the SOP. In the context of your project, the *Phytotitre* Project Guides and Method Sheets are the SOPs that should be followed. For example, if the SOP says "Incubate for 60 minutes", do not incubate for 45 or 75 minutes.

If a change to the SOP does occur during the conduct of an experiment, by accident or on purpose, for example due to a power cut, a spill or a reagent shortage, this is referred to as a **deviation**. All deviations must be recorded in your notes. A notebook that hides any such events is a violation of GLP. Acknowledging and recording clearly any errors that may have occurred (e.g. accidental pipetting of a reagent twice into a well) is a key principle of GLP work.

3. Equipment Calibration and Maintenance

An experiment is only as good as the tools used to measure it. We must make sure the equipment and instruments we use are working properly before completing any experiments.

Pipettes: Ensure they have been calibrated within the last 12 months. Always check for the calibration sticker.

Instrument servicing and QC reports: Many instruments require routine servicing to produce consistent measurements and remain reliable. Ensure the service record is up to date for any such items of equipment. Some instruments also perform a self-test on startup - keep a record of any such quality control reports.

Instrument logbooks: Major equipment (like microplate readers or flow cytometers) often have a usage log. Record your name, the date, and any errors the machine displayed.

Balances: Check the “Level” bubble on the analytical balance before weighing out your compounds when preparing solutions.

pH meter: Ensure the pH meter is calibrated with suitable standards (e.g. pH 4, pH 7, pH 10) before use.

4. Characterisation of test items

You should keep a record of the batch or lot ID for each kit or reagent you use, in both your lab notebook and any resulting electronic files. You should also strictly observe the storage requirements for any of the reagents you use (e.g., “store at -20°C, protect from light”), and ensure they are never cross-contaminated with other materials. Make sure such reagents are always used before the “best before” or “use by” date, or if used beyond that date, make an expicit note in your records that this was the case.

5. Reagent Labeling

A “mystery bottle” lacking a suitable label is both a safety hazard and a GLP failure. You should ensure that every sample or working stock reagent container is appropriately labelled with the following information:

1. Name and Concentration of the preparation (e.g., 10% SDS).
2. Date of Preparation.
3. Expiry Date (or "Use By" date).
4. Initials of the Preparer.
5. Storage Conditions (e.g., "Room Temp" or "4°C").
6. An appropriate hazard placard if required (e.g. a corrosive label for acids).

How to maintain a laboratory notebook to GLP standards

In a professional life science environment, your lab book is a legal document. It you make a breakthrough discovery, such as a new antibiotic or chemotherapy drug lead, the lab book is the evidence that proves when and how it happened. The following explains how to maintain your lab book to Good Laboratory Practice (GLP) standards, which you should use every time you write up your work from an experiment.

1. Begin with the date and project header

Begin each entry in your lab book by writing the full date. Then give the project title or number: e.g., Microbiology Project 01: *Phytotitre* Primary Screen. After this, give the experiment ID: This will be a code unique for that experiment on that day, e.g., CB-MP-001. This code should also be written on the lids of your 96-well plates, and present in your Excel data files.

2. Write the Objective

Write a one sentence statement of what you intend to achieve from the experiment. Example: "The aim is to screen Plate 1 of the *Phytotitre* library (Extracts 1-80) against *E. coli* DH5α to identify growth inhibitors."

3. Mention the Materials & Reagents

List the reagents or kits used, including Lot Numbers and Expiry Dates for each (e.g . *Phytotitre* kit Lot #16101). Also mention which equipment was used for any measurements (e.g. Thermo Fisher Multiskan Plate Reader).

4. Method

Mention which SOP you followed (e.g. *Phytotitre* Method Sheet 18). Note here also any deviations from that protocol and the reason (e.g., “Samples were incubated for 18 hours instead of 24 hours due to incubator availability”).

5. Results & Observations

Write in your notebook where the digital files for each of the raw absorbance measurements can be found (e.g. 20240104_E.coli_PT01_JB_exp4.xlsx). Record also any qualitative observations, e.g. “Well B4 showed unusual dark pigmentation” or “well volumes appeared lower than normal in column 7.”

6. Sign-off

Sign and date the bottom of the page. In industry, a supervisor would also “witness” this by also signing it.

7. Things you should NOT insert in your lab book

Personal notes: Do not record informal items, such as lunch plans, phone numbers, or jokes. Remember, the lab book is not only for you, it is also for your employer.

Large volumes of raw data: It is fine to write a short table of results (e.g. from disk diffusion assay measurements), but if a plate reader generates hundreds of numbers, do not copy or stick them all in the notebook. Reference instead the digital file location and insert the Summary Table or Graph.

Vague statements: Avoid "the experiment worked well." Use quantitative terms, such as: "The Z' factor was 0.72, indicating a robust assay."

8. Some key DOs and DON’Ts for GLP notebook entries

Feature	DO	DON’T
Ink	Use permanent blue or black ink.	Never use pencil or erasable pens.
Errors	Draw a single line through the error, initial, and date it.	Never use “Tipp-Ex,” white-out, or scribble over mistakes.
Empty Space	Draw a diagonal line through large blank spaces so nothing can be added later.	Never leave blank pages or large gaps between entries.
Attachments	Glue or tape in printouts and sign across the edge of the paper and the book page.	Never leave loose sheets of paper tucked into the book.
Timing	Record entries as you work (contemporaneously).	Never write up your notes at home at the end of the week.

Quality Assurance (QA)

In a professional GLP environment, a separate person (specifically responsible for Quality Assurance) will check your work against the respective SOP to ensure it has been conducted correctly. In your project, you can perform “Self-QA” by:

- Checking your plate maps twice before starting.
- Verifying your calculations (e.g. $C_1V_1 = C_2V_2$) with a peer or supervisor before making expensive dilutions.
- Ensuring your electronic files are backed up daily.
- Ensuring your laboratory notes meet GLP standards (see below)

Sustainable lab work

Research in the Life Sciences can be energy and resource intensive. We can improve the sustainability of our laboratory work by minimising the environmental footprint of our experiments in a way that does not compromise on scientific rigor. As a student, this means adopting a “LEAF” (Laboratory Efficiency Assessment Framework) mindset by planning experiments to minimise waste and ensuring energy-intensive equipment like incubators and plate readers are powered down after use, or at the end of the day (although be sure to check that no-one else is using the equipment before you switch it off).

Why adhering to these principles matters for your dissertation

Project examiners are look for “robustness” of your conduct and analysis. By including a paragraph in your methods section on how you managed Data Integrity and followed GLP principles, you demonstrate a level of professionalism that improves the chances of your submission receiving a Distinction-level pass.